CLAIMS

1. A device for measuring a level of a clinically relevant analyte in a fluid, including:

a flow path for conducting said fluid through the device;

a predetermined amount of said analyte arranged on said flow path such that the analyte mixes with fluid that passes it to form a calibration sample of the fluid;

detector means arranged on said flow path for detecting respective analyte levels in an unadulterated sample of the fluid and in the calibration sample.

2. A device according to claim 1 wherein said predetermined amount of analyte is arranged as part of the detector means.

3. A device according to either of the preceding claims wherein said detector means includes at least two detectors, a first of said detectors being arranged to detect the analyte level in the unadulterated sample, and a second of said detectors being arranged downstream of said predetermined amount of analyte to detect the analyte level in the calibration sample.

4. A device according to claim 3 wherein said first and said second detectors are arranged in series on the flow path, and said predetermined amount of analyte is located between said first and second detectors.

5. A device according to claim 3 wherein said flow path divides into at least two branches, said first detector being arranged on a first of said branches and the

predetermined amount of analyte and said second detector being arranged on a second of said branches.

6. A device according to claim 3 wherein there are two separate flow paths, said first detector being arranged on a first of said flow paths and the predetermined amount of analyte and said second detector being arranged on a second of said flow paths.

7. A device according to either of claims 1 or 2 wherein said flow path divides into at least two branches, said predetermined amount of analyte being located on one of said branches, and said branches rejoin upstream of the detector means and further wherein said branches are adapted so that fluid takes longer to flow through a first of said branches to the detector means than through a second of said branches.

8. A device according to claim 7 wherein the first and second branches are of different lengths.

9. A device according to claim 7 wherein the first and second branches have different flow rates.

10. A device according to any one of claims 7 to 9 wherein said predetermined amount of analyte is located said first branch.

11. A device according to any one of claims 7 to 10 wherein said detector means is a single detector.

12. A device according to any one of the preceding claims including a processor which is adapted to produce an analyte level reading by adjusting the analyte level

detected in the unadulterated sample according to the analyte level detected in said calibration sample.

13. A device according to any one of the preceding claims further including a second predetermined amount of said analyte arranged on said flow path such that it mixes with fluid that passes it to form a second calibration sample, and wherein said detector means is arranged on said flow path so as to detect an analyte level in an unadulterated sample, and in the calibration samples.

14. A device according to claim 13 wherein the predetermined amounts of said analyte are different amounts.

15. A device for measuring a level of a clinically relevant analyte in a fluid, the device including:

a flow path for conducting said fluid through the device;

a predetermined amount of a calibration analyte arranged on said flow path such that the calibration analyte mixes with fluid that passes it to form a calibration sample, the calibration analyte being a different species to said clinically relevant analyte;

first detector means arranged on said flow path for detecting a level of said clinically relevant analyte in the calibration sample; and

second detector means arranged on said flow path for detecting a level of said calibration analyte in the calibration sample.

16. A device according to claim 15 wherein the calibration analyte is a substance which is not naturally

present in the fluid or which is only naturally present at low levels.

17. A device according to claim 15 or claim 16 wherein the calibration analyte is either a substrate of the enzyme class of oxidoreductases acting on the CH-OH group of donors with oxygen as an acceptor or a substrate of a synthetic enzymes such as a catalytic antibody.

18. A device according to any one of claims 15 to 17 wherein the first and second detector means are arranged on a single channel of the flow path.

19. A device according to claim 18 wherein the first and second detector means are arranged at the same location on the flow path.

20. A device according to any one of the preceding claims wherein said clinically relevant analyte is glucose.

21. A device according to any one of the preceding claims wherein said detector means includes at least one enzyme electrode.

22. A device according to any one of the preceding claims further including a processor for processing signals from said detector means to produce an analyte level reading.

23. A device according to claim 22 further including a sensor connected to said processor, wherein the processor also processes signals from said sensor to produce an analyte level reading.

24. A device according to any one of the preceding claims wherein said flow path operates to draw the fluid through the device by capillary action.

25. A method for testing, in a portable device, levels of clinically relevant analytes in a fluid including the steps of:

mixing a sample of the fluid with a known amount of said analyte to form a calibration sample;

measuring the analyte level in an unadulterated sample of the fluid;

measuring the analyte level in said calibration sample; and

adjusting the analyte level measured in said unadulterated sample using the analyte level measured in said calibration sample.

26. A method according to claim 25 further including the step of generating an analyte level reading from said adjusted analyte level, wherein said step of adjusting is carried out on the unprocessed measurement of the analyte level in the unadulterated sample.

27. A method according to either of claims 25 or 26 further including the step of generating an analyte level reading from the measurement of the analyte level in the unadulterated sample, wherein said step of adjusting is carried out on the analyte level reading.

28. A method according to claim 26 or claim 27 wherein the analyte level reading is generated by applying a calibration curve to the analyte level.

29. A method according to any one of claims 25 to 28 wherein in the adjusting step, the expression used to calculate an adjusted analyte concentration is:

$$Gl_{adj} = (Gl_{un} \times Q)/(Gl_{cal} - Gl_{un})$$

where Gl_{adj}, Gl_{un} and Gl_{cal} are respectively the adjusted analyte concentration, the analyte concentration measured in the unadulterated sample of the fluid, and the analyte concentration measured in the calibration sample and Q is the known increase in concentration of analyte in the calibration sample resulting from the addition of a known amount of analyte to a known volume of sample.

30. A method according to any one of claims 25 to 29 further including the steps of mixing a sample of the fluid with a second known amount of analyte to form a second calibration sample, and measuring the analyte level in said second calibration sample, wherein the step of adjusting uses the analyte levels measured in both calibration samples.

31. A method according to claim 30 wherein the sample of fluid which is mixed with the second known amount of analyte is of a known volume.

32. A method for testing, in a portable device, levels of a clinically relevant analyte in a fluid, including the steps of:

mixing a known amount of a calibration analyte into a sample of said fluid, the calibration analyte being a different species to said clinically relevant analyte;

measuring the level of said clinically relevant analyte in said sample;

measuring the level of said calibration analyte in

said sample;

adjusting the measured level of said clinically relevant analyte using the measured level of said calibration analyte.

33. A method according to claim 32 wherein the calibration analyte is a substance which is not naturally present in the fluid or which is only naturally present at low levels.

34. A method according to claim 32 or claim 33 wherein the calibration analyte is either a substrate of the enzyme class of oxidoreductases acting on the CH-OH group of donors with oxygen as an acceptor or a substrate of a synthetic enzyme such as a catalytic antibody.

35. A method according to any one of claims 25 to 34 wherein the clinically relevant analyte is glucose.

36. A method according to any one of claims 25 to 35 wherein the fluid is blood.

37. A method according to any one of claims 25 to 36 wherein said steps of measuring involve measuring a concentration of analyte.

38. A method according to any one of claims 25 to 37 wherein in said step of mixing, a known volume of fluid is mixed with the known amount of said analyte.

39. A method according to any one of claims 25 to 38 further including the step of introducing said fluid to a flow path, and wherein said fluid flows along the flow path whilst said steps of measuring and mixing are carried out.

40. A method according to any one of claims 25 to 39 wherein said step of adjusting includes making corrections based on one or more external factors.

41. A method according to claim 40 wherein at least one of said external factors is the ambient temperature.